



COMMONWEALTH OF VIRGINIA
Department of Health

ROBERT B. STROUBE, M.D., M.P.H.
STATE HEALTH COMMISSIONER (ACTING)

OFFICE OF ADJUDICATION

DOUGLAS R. HARRIS, J.D.

**RECOMMENDATION TO THE STATE HEALTH COMMISSIONER
REGARDING CERTIFICATE OF PUBLIC NEED (COPN)
REQUEST NUMBER VA-6565
CJW JOHNSTON-WILLIS MEDICAL CENTER
CHESTERFIELD COUNTY
INTRODUCTION OF GAMMA KNIFE SURGERY AND
CAPITAL EXPENDITURE IN EXCESS OF \$5 MILLION**

A. FINDINGS OF FACT

1. On July 2, 2001, Chippenham & Johnston-Willis Hospitals, Inc., a two-hospital, for-profit corporation owned by Hospital Corporation of America (HCA), applied for a certificate of public need (COPN), seeking authorization to introduce gamma knife surgery and to implement improvements collectively constituting a capital expenditure exceeding five million dollars at CJW Johnston-Willis Medical Center (CJW) in Chesterfield County, in Planning District (PD) 15, Health Planning Region (HPR) IV.
2. The Central Virginia Health Planning Agency (CVHPA) serves HPR IV by reviewing “projects,” as defined in Section 32.1-102.1 of the Virginia Code, proposed for location within the boundaries of HPR IV.
3. Sections 32.1-102.1 and 32.1-102.3 of the Code of Virginia require that the “[i]ntroduction into an existing medical care facility of any services” and “[a]ny capital expenditure of five million dollars or more, not defined as reviewable . . . [elsewhere in this chapter], by or in behalf of a medical care facility” must be approved by the State Health Commissioner through issuance of a COPN.
4. The entire project proposed for CJW includes three aspects: (i) introduction of a gamma knife facility; (ii) construction of a neuroscience and outpatient diagnostic center – to include the gamma knife facility among others; and (iii) construction of a three-story, 700-space parking deck. The

projected total capital cost of this combined proposal is \$20,593,137, including approximately \$3.2 million for the gamma knife, \$4.2 million for the diagnostic center's construction and equipment, and \$13.2 for the parking deck and architectural and engineering fees.

5. Virginia regulation, *viz.*, 12 VAC 5-220-10 – a provision within the State Medical Facilities Plan (SMFP), defines “gamma knife surgery” to mean “stereotactic radiosurgery, where stereotactic radiosurgery is the noninvasive therapeutic procedure performed by directing radiant energy beams from any source at a treatment target in the head to produce tissue destruction.”

6. The SMFP, at 12VAC5-340-90, contains a standard requiring that the average annual number of procedures performed at gamma knife facilities in the Commonwealth should be 475. This standard was adopted in 1993. CJW asserts that only two percent of gamma knife facilities in the country perform in excess of 400 procedures annually.

7. Gamma knife surgery involves directing more than 200 high-energy radiation beams to a targeted point within the brain, corresponding to the location of a tumor or lesion. Each individual beam contains a low dose of radiation, avoiding damage to healthy brain tissue. Gamma knife treatment is a non-invasive procedure requiring only local anesthesia to fix a lightweight frame to the outside of the patient's skull. By contrast, craniotomy is a traditional surgical procedure that involves general anesthesia, shaving the head, drilling burr holes into the skull, sawing out a section of the skull, using coagulation techniques to prevent hemorrhage, descending into the brain with various surgical instruments, and using a laser or other microscopic equipment to remove tumors or to perform other procedures in the brain. Gamma knife treatment has been applied successfully to a number of neurological conditions. In recent years, the number of treatable conditions has grown, as improvements in technique and expanding research reveals additional opportunities.

8. The Chippenham and Johnston-Willis campuses, *i.e.*, Chippenham Medical Center and CJW together have 748 general hospital beds. The CJW campus is an acute care hospital located on a 34-acre parcel in Chesterfield County. HCA is a for-profit entity, incorporated in Tennessee. HCA owns and operates approximately 200 hospitals and other healthcare facilities in 24 States, and in England and Switzerland. HCA owns or operates 15 facilities in Virginia, including CJW and Henrico Doctors' Hospitals in Henrico County, PD 15.

9. Johnston-Willis Hospital, now CJW, was established in 1909 in downtown Richmond. HCA purchased the facility in 1968; in 1980, the hospital relocated to its current facility in Chesterfield County. CJW's 282 licensed, inpatient bed complement is composed of 178 medical-surgical, 10 pediatric, 39 obstetric, 21 intensive care unit (ICU), and 34 rehabilitation beds. CJW is designated as a Level III Trauma center and is accredited by the American College of Surgeons as a community hospital comprehensive cancer program. Approximately 580,200 people live in CJW's primary service area.

10. The International Radiosurgery Support Association (IRSA), with primary offices in Harrisburg, Pennsylvania, has written in support of CJW's application, noting that it has identified Virginia as “an under-served population for gamma knife treatments,” and that CJW would be an “excellent geographic location” for the establishment of a gamma knife facility.

11. As the following table shows, in 1999, CJW ranked fourteenth of the eighteen hospitals in HPR IV for its contribution to charity care, expressed as a percentage of gross patient revenue. In 1997, CJW provided less than 0.01 percent. In 1998, it met the median of 0.7 percent, and in 1999 its contribution fell to 0.3 percent.

**Charity Care Percentage of Gross Patient Revenue
in Health Planning Region IV, 1998 and 1999**

Facility	1998	1999
Medical College of Virginia Hospital	17.5	17.2
Southside Community Hospital	3.1	3.2
Community Memorial Healthcenter	3.4	2.6
Bon Secours – Richmond Community Hospital	0.4	2.0
Southside Regional Medical Center	1.7	1.5
Halifax Regional Hospital	1.6	1.5
Children's Hospital	1.2	1.0
Capitol Medical Center	0.7	0.8
John Randolph Hospital	0.7	0.7
Bon Secours-Stuart Circle Hospital	0.8	0.6
St. Mary's Hospital	0.5	0.5
Richmond Eye & Ear Hospital	0.3	0.5
Retreat Hospital	0.6	0.5
<i>Chippenhams & Johnston-Willis Hospitals</i>	0.7	0.3
Henrico Doctors' Hospital	0.4	0.3
Memorial Regional Medical Center*	n/a	0.3
HealthSouth Medical Center**	0.0	0.0
Greensville Memorial Hospital	2.1	n/a
Richmond Memorial Hospital***	0.5	n/a
HPR Median	0.7	0.7

* Opened in 1999

** Purchased by HCA in 2001

*** Closed in 1999

12. CVHPA's calculations of the median percentage deviate from the Department's insofar as CVHPA identifies a median percentage of charity care provided in PD 15 of 0.8 percent in 1999 and 0.9 for HPR IV in 1999. CVHPA calculates the mean, or average, percentage of charity care provided in PD 15 to be 2.2 percent in 1999 and to be 2.1 percent for HPR IV in the same year.

13. CJW anticipates that patients from outside the Richmond area would travel to CJW in order to undergo gamma knife surgery, indicating that the service would have a regional service area.

14. By letter dated October 19, 2001, the Virginia Department of Health, Division of Certificate of Public Need (DCOPN) notified CJW that DCOPN recommends partial approval of the application, *i.e.*, approval of the proposal to construct a diagnostic center and a parking deck, and denial of the introduction of gamma knife surgery.

15. An IFFC was convened on October 30, 2001, in Richmond pursuant to Sections 2.2-4019 and 32.1-201.6 of the Virginia Code to discuss this application. CJW was represented by counsel at the IFFC.

B. DISCUSSION OF THE APPLICATIONS IN RELATION TO THE LAW

Virginia Code Section 32.1-102.3 B requires that, in determining whether a public need for a proposed project has been demonstrated, the State Health Commissioner shall review an application for a certificate of public need in relation to the twenty considerations enumerated in that section. The following is a discussion of the applications in relation to these considerations.

1. The recommendation and the reasons therefor of the appropriate regional health planning agency.

On October 3, 2001, the Board of the Central Virginia Health Planning Agency (CVHPA) voted unanimously to recommend approval of the proposed project, provided the applicant agrees to:

- (i) Provide neuroscience and outpatient diagnostic services to all patients without regard to ability to pay, as evinced by –
 - (a) The provision of general neuroscience and outpatient diagnostic services as charity care equating to a level of at least 0.8 percent of gross patient revenue,
 - (b) The provision of gamma knife surgery as charity care equating to a level of at least two percent of gross patient revenue; and
 - (c) The maintenance of a written log to document charity care; and
- (ii) Demonstrate through documentation that each neurosurgeon who would employ the gamma knife facility is properly credentialed for such procedures.

Following discussions with CJW, CVHPA voted to recommend denial of the application, due to CJW's decision not to agree to the specific condition that gamma knife surgery be provided at a level of two percent of patient revenue. At the IFFC, CJW represented that it agrees to all conditions relating to charity care devised by CVHPA except this one.

2. The relationship of the project to the applicable health plans of the regional health planning agency, the Virginia Health Planning Board and the Board of Health.

The applicable health plan is the portion of the State Medical Facilities Plan (SMFP) found in Part III of Chapter 340 and Chapter 350 of Title 12 (Agency 5) the Virginia Administrative Code (VAC, 12 VAC 5-340-10 *et seq* and -350-10 *et seq*). (Text appearing under this consideration in italics has been selected from the SMFP and precedes discussion of the proposed project in relation to the selected text.)

12 VAC 5-340-80. Accessibility; travel time; financial considerations. A. Gamma Knife services should be located so as to optimize accessibility for all Virginia residents.

CJW is located on Midlothian Turnpike in Chesterfield County. It is accessible by either Powhite Parkway or Chippenham Parkway – major highways developed to serve as conduits linking

Interstates 64 and 95 with the older road structure. By use of these highways, the facility is generally accessible to many residents living outside central Virginia.

The International Radiosurgery Support Association (IRSA), with primary offices in Harrisburg, Pennsylvania, has written in support of CJW's application, noting that CJW is an "excellent geographic location" for the establishment of a gamma knife facility.

CJW has an open medical staff, *i.e.*, qualified physicians who normally practice at other hospitals but who wish to use the gamma knife for their patients may apply for, and obtain, privileges to perform gamma knife procedures on their patients at CJW. Additionally, CJW has expressed willingness to train neurosurgical residents on the gamma knife unit.

B. Gamma Knife services should be accessible to all patients in need of the services without regard to ability to pay or payment source.

As noted above, CJW failed in 1999 to meet the median level of charity care prevailing in HPR IV. CJW provided charity care at the median amount in 1998, but in 1997 provided a level of charity care less than 0.01 percent of gross patient revenue. Such a contribution to the health of the community's most needy is meager.

Following the IFFC, CJW agreed to provide free or discounted gamma knife services to uninsured patients with incomes at or below 200 percent of the federal poverty guidelines in an amount equal to 1.5 percent of gross gamma knife charges.

CJW states that the Centers for Medicare and Medicaid Services has designated CJW as a "disproportionate share" hospital of services to low income patients, pursuant to federal regulation, *viz.*, 42 CFR 412.106. While this designation is notable, such designation exists to afford a hospital "special treatment" and a "payment adjustment," according to the federal regulation. For present purposes, this designation does nothing to enhance the low level of charity care CJW provides.

12 VAC 5-340-90. Availability; need for new service. No new Gamma Knife surgery services should be approved unless: (i) the number of procedures performed with existing units in the Commonwealth average more than 475 per year; and (ii) it can be reasonably projected that the proposed new service will perform at least 250 Gamma Knife surgery procedures in the third year of operation.

The State Board of Health adopted this standard in 1993. Available data indicate that only 56 percent of gamma knife facilities in the country perform between 100 and 200 procedures annually, and that only two percent of gamma knife facilities in the country perform in excess of 400 procedures annually. According to the International Radiosurgery Support Association (IRSA), the national average performed by each facility is 170 gamma knife treatments per year.

The University of Virginia Hospitals – the only facility in the Commonwealth possessing a gamma knife unit – performs fewer than 350 procedures annually, and a substantial number of those procedures are performed on patients residing outside Virginia. The six facilities in Virginia possessing linear accelerators with stereotactic radiosurgery (including CJW) each performed fewer than 50 procedures annually. (Stereotactic radiosurgery using a linear accelerator, or LINAC

radiosurgery, is appropriate for many conditions, but is less powerful, less precise and less accurate in targeting brain lesions than gamma knife surgery, and may involve more side effects than gamma knife treatment.) CJW argues that the 475 procedure standard in the SMFP should be “set aside” as inaccurate, outdated, inadequate, or otherwise inapplicable pursuant to Virginia Code Section 32.1-102.3 (A).

CJW projects that it will perform at least 250 gamma knife procedures by the third year of operation and states that this projection is conservative. According to IRSA, at least 232, and perhaps as many as 386, Virginia residents traveled outside the Commonwealth to receive gamma knife treatment during the 12-month period from July 1, 2000, to June 30, 2001. About half of these patients, according to IRSA, reside within 20 miles of Richmond or Petersburg.

IRSA estimates that 2,500 Virginia residents each year could benefit from gamma knife treatment, and observes that gamma knife treatment “is currently considered the *standard of care* throughout the world as an alternative to open skull craniotomy. [Emphasis in the original].”

About 300 Virginia residents are diagnosed annually with trigeminal neuralgia (TN), which can be treated using a gamma knife, according to the group leader for the Mid-Virginia Trigeminal Neuralgia Support Group, who himself faces the challenge of this neurological condition and who testified candidly regarding his personal medical experiences at the IFFC. TN, like many other neurological conditions, is a painful condition that limits patients’ ability to travel long distances for treatment. IRSA estimates that each gamma knife facility in the country treats at least 20 TN patients annually.

12 VAC 5-340-100. Continuity; coordination of services; tumors registry; discharge and follow-up. A. Facilities providing Gamma Knife surgery services should have an established neurosurgery program and a complete range of therapeutic radiation services.

CJW has an established neuroscience program offering a wide range of neuroscience services, including special studies; interventional radiology; inpatient and outpatient occupational, speech, and physical therapies; and stereotactic capabilities. CJW also has a dedicated neurosurgery operating room suite equipped with special neurosurgery equipment and staffed by dedicated neurosurgery nurses. Further, it has a dedicated neuroscience intensive care unit (ICU), a medical-surgical floor, a radiology department providing a range of diagnostic services, including computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET). CJW also provides inpatient medical rehabilitation for neuroscience patients.

IRSA notes that data and research clearly indicate that patients benefit when treated in a hospital that offers a continuum of neurosurgical treatments, consisting of microsurgery, LINAC radiosurgery (performed in one session), LINAC radiotherapy (performed over several days or weeks), and gamma knife surgery. Currently, CJW offers all such treatments excepting gamma knife surgery.

B. Facilities providing Gamma Knife surgery services should participate in an accredited tumor registry.

Since 1983, CJW has participated in the Virginia Cancer Registry, the national tumor registry accredited by the American College of Surgeons.

C. 1. All Gamma Knife surgery services should have written procedures and policies for discharge planning and follow-up care for the patient and family as part of the institution's overall discharge planning program.

CJW is an acute care hospital owned by a corporation with a wealth of resources in developing such things as policies and procedures for discharge planning and follow-up care. It should face no obstacle in developing such documents for the proposed service.

2. All Gamma Knife surgery services should have established protocols for referring physicians to assure adequate post-operative diagnostic evaluation for radiosurgery patients.

CJW has established practices, required by professional and regulatory guidelines, for neurosurgeons who perform radiosurgery procedures to oversee the post-operative care of their patients, including appropriate post-operative diagnostic evaluations. These are currently-effective guidelines used by the medical staff at CJW and would only need to be revised to include gamma knife services. Additionally, CJW has an open medical staff. Physicians who are properly trained in using a gamma knife and who wish to perform gamma knife procedures may request and obtain privileges through the CJW's credentialing process.

12 VAC 5-340-110. Cost comparability. A. The total costs of providing Gamma Knife surgery services projected by prospective providers should be comparable to the costs of other similar service providers in the state. B. The usual and customary charge to the patient for Gamma Knife surgery should be commensurate with cost.

CJW projects the charge for a gamma knife procedure to be \$29,440, and the cost to be \$11,879 in 2004. CJW's projected charges are comparable to those of existing gamma knife providers, including the University of Virginia Hospitals. Data from IRSA indicate that the national average charge for gamma knife treatment is between \$35,000 and \$45,000, with a median of \$39,000. Reimbursement from Medicare and third-party payors for inpatient and outpatient gamma knife procedures range from \$7,000 to \$25,000.

When a facility's charge for a procedure is disproportionately higher than the cost and prevailing reimbursement for that procedure, patient accessibility may be compromised and overall costs to the community may be higher. Such a procedure is less affordable to those patients who contractually pay a percentage of a charge and markedly less affordable to the uninsured.

12 VAC 5-340-120. Quality; staffing; equipment. A. 1. Gamma Knife surgery programs should have a medical director who is board certified in neurosurgery, with experience in all phases of Gamma Knife surgical procedures.

CJW represents that the medical director for the proposed gamma knife service would be a board certified neurosurgeon. All neurosurgeons currently on staff at CJW are board certified or board eligible in neurosurgery.

2. In addition to the medical director, all Gamma Knife surgery programs should have a radiation physicist who is certified in radiology, or who holds an advanced degree in physics with two to three years full-time radiation therapy experience working under the direction of a radiation therapist, present for each Gamma Knife surgery procedure performed.

CJW currently has a nuclear physicist who is certified in radiation therapy physics by the American Board of Radiology and has ten years of full-time radiation therapy experience, including experience performing gamma knife procedures.

3. The staffing pattern for the team performing each Gamma Knife surgery procedure should be composed of at least the following nonphysician personnel with experience in Gamma Knife procedures: (i) radiotherapists; (ii) radiation technologists; and (iii) a clinical registered nurse.

The prevailing standard for composing a gamma knife team consists of a neurosurgeon, a radiation oncologist, a physicist, and a registered nurse. CJW proposes to adopt this model and thereby construct a team comprised of clinicians with more advanced skills than those required by the SMFP.

B. 1. Facilities providing Gamma Knife surgery services should have dosimetry and calibration equipment and a computer with appropriate software for performing Gamma Knife surgery procedures.

The necessary calibration and computer equipment comes as a standard component of the gamma knife armamentarium. CJW already has a dosimetry program in place.

2. Facilities providing Gamma Knife surgery services should also have access to magnetic resonance imaging, computed tomography, and angiography services.

CJW offers MRI, CT, angiography, and PET services.

12 VAC 5-350-20. Project need. All proposals involving the expenditure of . . . [five] million dollars or more by a medical care facility should include documentation that the expenditure is necessary in order for the facility to meet identified medical care needs of the public it serves. Such documentation should clearly identify that [edited to reflect a de facto amendment effected by a 1996 change in statutory law]:

- 1. The expenditure can be reasonably related to the service mission or business plan of the facility;*
- 2. The expenditure represents the most cost-effective approach to meeting the identified need; and*
- 3. The expenditure and the ongoing operational costs related to the capital expenditure will not result in unreasonable increases in the cost of delivering the services provided by the facility.*

CJW opened its doors in its present facility, formerly Johnston-Willis Hospital, in 1980. The applicant contends that, as the hospital has aged and healthcare delivery has changed, the facility has

become less effective in providing health care. CJW contends that “[the neuroscience and outpatient diagnostic center aspect of t]his project will enhance the ability of CJW to offer high quality patient care in its outpatient diagnostic services and its [proposed] neuroscience [and diagnostic] center.” Further, CJW believes that “[c]onsolidating various services in the center will provide scheduling advantages, operational efficiency, and reduced patient confusion,” as fragmented services are consolidated according to present exigencies, patterns of care and expectations.

Many neuroscience patients have reduced mobility. The diagnostic center will include space for a variety of services for patients who suffer from neurological conditions such as stroke, brain tumors, multiple sclerosis (MS), Parkinson’s disease, seizures, brain injury, and other conditions that require neck and back surgeries. They will benefit from the increased accessibility offered by the ground-floor diagnostic center and the nearby parking deck.

CJW states that the number of inpatient, emergency department, and outpatient visits is increasing and this presents a definite, identified difficulty in finding parking spaces. The parking deck, for which no clear alternative exists, will allow greater access to the remainder of the facility, as well as the diagnostic center.

This physical expansion project would be funded through accumulated reserves, but the project may increase the cost per patient day by \$50 to \$70 over the next four years. The project appears reasonable insofar as net revenues would likely mitigate against some of the expense of the project, as the enhanced facility and additional service would generate revenue. The projected increase in average cost, calculated by patient day, would be six to eight percent.

12 VAC 5-350-30. Facilities expansion. Proposals for the expansion of medical care facilities should document that the current space provided in the facility for the areas or departments proposed for expansion are inadequate. Such documentation should include:

- A. An analysis of the historical volume of work activity or other activity performed in the area or department;*
- B. The projected volume of work activity or other activity performed in the area or department;*
- C. Evidence that contemporary design guidelines for space in the relevant areas or departments, based on levels of work activity or other activity, are consistent with the proposal; and*
- D. A comparative analysis of the space provided in the relevant areas and departments of other similar medical care facilities in the planning district and/or health planning region.*

The application includes documentation showing significant growth in neuroscience services [e.g., physical therapy, occupational therapy and speech therapy, electromyogramography (EMG), electroencephelogramography (EEG)] and diagnostic imaging services (e.g., mammography, CT, x-ray and ultrasound) at CJW during recent years. CJW’s volume of neuroscience procedures is growing.

The neuroscience and diagnostic center will provide improved patient flow as well as patient and family member privacy while meeting current design and construction guidelines and expectations. CJW represents that “[s]pace within the center will be planned, designed, and

constructed to meet and, as appropriate, exceed the minimum requirements for hospital design and construction as specified within building codes and planning standards. Within the past 15 years, several of the codes that apply to hospital construction have been revised. Many have instituted more stringent requirements.” CJW states that applicable building codes and space standards for development of hospitals and healthcare facilities will be used to identify the minimum space required for each of the services.

12 VAC 5-350-50. Equipment. Proposals for the purchase and installation of equipment by medical care facilities which are not specifically addressed in another component of the SMFP should document that the equipment is needed. Such documentation should clearly indicate (i) that the proposed equipment is needed to maintain the current level of service provided by the facility; or (ii) if the equipment involves the provision of a new service or an increase in the quantitative or qualitative level of an existing service provided by the facility, that the benefits of the change in service resulting from the new equipment exceed the costs of purchasing (leasing) and operating the equipment over its useful life.

CJW maintains that all proposed equipment is necessary. Existing equipment would be used where appropriate. Since the project involves reconfiguration of some areas, however, some new equipment and supplies will be necessary. Outdated equipment that has completed its useful life cycle would be replaced. All existing equipment that meets standards of care will be appropriately relocated and used.

Costs for new equipment are included in the capital costs associated with the project. The proposal includes \$7.5 million for equipment. About \$3.2 million of this total will be used to purchase the gamma knife, and the remainder will be used to purchase the outpatient imaging equipment, including five mammography, two ultrasound, and two EEG units, and one EMG, x-ray, biopsy and bone densitometry unit.

12 VAC 5-350-60. Assurances. [Not applicable.]

3. The relationship of the project to the long-range development plan, if any, of the person applying for a certificate.

The project appears consistent with CJW’s long-range plan. CJW’s mission statement focuses on the continued development of current technologies to provide appropriate care to patients. In particular, the addition of gamma knife services is consistent with CJW’s mission and reflects the desire to add technology to treat patients in situations when its current stereotactic radiosurgery technology fails to be appropriate.

4. The need that the population served or to be served by the project has for the project, including, but not limited to, the needs of rural populations in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

As discussed in detail above, the availability of gamma knife treatment at CJW would likely enhance the choices available to patients and expand the options available for the families who support those patients. The availability of gamma knife services would be particularly beneficial to Virginia residents who currently obtain gamma knife treatment outside of the Commonwealth. According to the International Radiosurgery Support Association (IRSA), at least 232, and perhaps as many as 386,

Virginia residents traveled outside the Commonwealth to receive gamma knife treatment during a 12-month period from July 1, 2000, to June 30, 2001.

CJW estimates that 808 patients in Virginia are potential candidates for gamma knife treatment. The greatest annual volume of UVA's gamma knife procedures, however, has been 335, including many patients from outside Virginia and the U.S. The proposed gamma knife may not be optimally utilized.

According to information provided by Elekta Instruments – the manufacturer of the gamma knife, 36 states in the U.S. have at least one gamma knife and twelve of these 36 states have two or more gamma knives. The 2000 U.S. census shows that Virginia's population exceeds seven million, placing it twelfth in order of magnitude among the states. IRSA has identified Virginia as "an underserved population for gamma knife treatments," and notes that CJW would be an "excellent geographic location" for the establishment of a gamma knife facility. Establishment of gamma knife surgery at CJW would reduce the challenges of travel for local and regional neurological patients, many of whom experience considerable pain, and would complete a continuum of neurosurgical care, as noted above.

As discussed in detail above, the neuroscience and diagnostic center promises to improve significantly the quality, appropriateness and convenience of many services providing neurological and outpatient care. The proposed facility would be more accessible to patients and the dedicated outpatient facility would better serve patients by reducing waiting times, rescheduling, and confusion. CJW has provided detailed documentation indicating a significant need for additional parking space, such as the proposed 700-space parking deck would provide.

5. The extent to which the project will be accessible to all residents of the area proposed to be served.

CJW is be geographically accessible to central Virginia patients via major roadways, air travel and rail. CJW's performance as a provider of charity care was below the median in 1999. CJW asserts, however, that its "commitment to providing indigent care makes it accessible to patients of all economic backgrounds. CJW's outreach programs with local free clinics, including the Cross-over Ministries, Fan Free Clinic and Irvin Gammon Craig Medical Center, further expand CJW's accessibility to low income patients."

6. The area, population, topography, highway facilities and availability of the services to be provided by the project in the particular part of the health service area in which the project is proposed, in particular, the distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

CJW is located in Chesterfield County near its boundary with the City of Richmond. The area is rolling hills and is densely populated. CJW is easily accessible via the Powhite Parkway and Midlothian Turnpike, major roads that connect with Interstates 95 and 64, and by public transportation.

The population growth rate for the area has been significant over the last ten years. The 2000 U.S. Census indicates that Henrico and Chesterfield counties – the third and fourth most populous

counties in Virginia, respectively, experienced a growth rate of 20.4 and 24.2 percent from 1990 to 2000, respectively. CJW identifies a primary service area with a population of 580,200.

7. Less costly or more effective alternate methods of reasonably meeting identified health service needs.

While the alternative to establishment of gamma knife surgery at CJW exists in maintaining the existing scenario, locating a gamma knife at CJW, with the superior precision of this technology, compared to craniotomy or treatment using a linear accelerator, would likely result in improved outcomes, reduced morbidity and mortality, fewer complications, and lower radiation directed at normal structures of the brain. Craniotomy and existing treatment may complement gamma knife technology for some neurological conditions, but they are not alternatives to it in many cases. IRSA, as noted above, observes that gamma knife surgery has become the standard of care worldwide as an alternative to craniotomy.

The alternative to the neuroscience and diagnostic center is to keep the various neuroscience and outpatient diagnostic services distributed throughout various clinical departments at CJW and continue to mix outpatient, inpatient, and emergency patient populations in a less than fully efficient pattern. CJW has no apparent alternative to building the proposed parking deck, if it is to meet the need of its patients to have reasonably convenient access to the hospital's various facilities.

8. The immediate and long-term financial feasibility of the project.

The project, to be prosecuted using accumulated reserves, appears financially feasible. CJW, and its parent corporation – HCA, clearly have sufficient resources for the development and operation of the overall project. continued population growth in the service area further indicates an immediate and long-term need for services and the financial feasibility of the project.

Further, the marketing opportunity to CJW of having the gamma knife service, along with a consolidated neuroscience and outpatient diagnostic center and enhanced parking facilities, constitute an intangible, but likely realizable, benefit. At the public hearing on this application, three prominent neurologists practicing in the central Virginia area shared their belief that sufficient volume exists to support CJW's projections of gamma knife utilization and feasibility at CJW.

9. The relationship of the project to the existing health care system of the area in which the project is proposed; however, for projects proposed in rural areas, the relationship of the project to the existing health care services in the specific rural locality shall be considered.

HPR IV is served by 15 other hospitals, including the Medical College of Virginia Hospitals – a large academic medical center that has a linear accelerator with stereotactic radiosurgery capability. MCV's chairman of neurosurgery has written in support of CJW's application.

UVa, located in HPR I, is Virginia's only current provider of gamma knife surgery – a technology that performs stereotactic radiosurgery more powerfully and precisely than radiosurgery performed using a linear accelerator. UVa, however, is located over an hour's drive from northern Chesterfield County and has a closed faculty, or staff, necessitating the referral of many patient to that facility from without.

CJW plans to have an open faculty, or staff, in relation to the proposed gamma knife service, meaning, as related by CJW's chief of neurosurgery, that "any neurosurgeon, . . . [whether practicing medicine in] Norfolk, Tidewater, [or elsewhere] as long as he is well-trained and certified to do gamma knife, can travel with his patients."

The introduction of gamma knife surgery at CJW may dilute the efficiency and effectiveness of the service at UVA; however, the record contains no indication of any overt opposition to CJW's application. Further, a health system's continued reliance on the ability to refer patients outside its region does little to assuage the attendant issues, including challenges relating to travel and to continuity of care. At the public hearing on this application, a prominent neurologist practicing in the Richmond area discussed the importance of continuity of care and the problems caused by disruption in the care of his patients having to go elsewhere for gamma knife surgery.

The construction of a relocated neuroscience and outpatient diagnostic center, as well as the construction of a parking deck will not add new services to the health care system, but will assist CJW in providing its existing and proposed services.

10. The availability of resources for the project.

CJW, and HCA – its parent corporation, clearly have adequate fiscal, human and technological resources to implement this project and maintain the resulting services effectively.

11. The organizational relationship of the project to necessary ancillary and support services.

CJW is a large general acute-care hospital that offers comprehensive ancillary and support services. CJW has an established neuroscience service, as well.

12. The relationship of the project to the clinical needs of health professional training programs in the area in which the project is proposed.

Although CJW is not a teaching hospital, it has expressed willingness to train neurosurgical residents on the gamma knife unit.

13. The special needs and circumstances of an applicant for a certificate, such as a medical school, hospital, multidisciplinary clinic, specialty center or regional health service provider, if a substantial portion of the applicant's services or resources or both is provided to individuals not residing in the health service area in which the project is to be located.

Not applicable.

14. The special needs and circumstances of health maintenance organizations. When considering the special needs and circumstances of health maintenance organizations, the Commissioner may grant a certificate for a project if the Commissioner finds that the project is needed by the enrolled or reasonably anticipated new members of the health maintenance organization or the beds or services to be provided are not available from providers which are

not health maintenance organizations or from other health maintenance organizations in a reasonable and cost-effective manner.

Not applicable.

15. The special needs and circumstances for biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

Not applicable.

16. In the case of a construction project, the costs and benefits of the proposed construction.

The capital costs of the proposed neuroscience and outpatient diagnostic center and the parking deck appear appropriate relative to the benefits to patients and staff that should accrue as a direct result of the project. The proposed neuroscience and outpatient diagnostic center would allow the routing of CJW's general outpatient population and its inpatient population separately. Development of this center will provide benefits such as the efficient circulation of patients, physicians and staff, and centralized facilities for outpatient diagnostics.

17. The probable impact of the project on the costs of and charges for providing health services by the applicant for a certificate and on the costs and charges to the public for providing health services by other persons in the area.

Although the overall project will be funded through CJW's accumulated reserves, it may minimally CJW's costs and charges to the public. The number of patients treated by CJW, however, is increasingly annually by about two percent and the proposed facility, especially the diagnostic imaging aspect of the outpatient center, should increase revenues. CJW's projected gamma knife charges are below the current national average.

18. Improvements or innovations in the financing and delivery of health services which foster competition and serve to promote quality assurance and cost effectiveness.

The proposed project would likely improve patient care through the consolidation of outpatient services into a single facility, thereby improving accessibility, decreasing waiting times and confusion, and reducing outpatients' inconvenience due to being "bumped" by emergent patients' needs. The gamma knife service may promote quality by enabling more patients to benefit from a non-invasive, highly accurate technique to treat certain neurological conditions. CJW's location in central Virginia and its open medical staff should benefit neurological care generally by enabling neurosurgeons to provide gamma knife treatment, as well as follow-up care, to their neurological patients.

19. In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities in the area similar to those proposed, including, in the case of rural localities, any distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

Utilization of the gamma knife facility at UVa currently stands at about 50 percent of the 1993 SMFP standard. This standard was devised before gamma knife service levels achieved their present level of equilibrium. As noted above in relation to the discussion of 12 VAC 5-340-90 under the second statutory consideration, fewer than two percent of gamma knife facilities nationwide approach the SMFP standard. No clear basis exists on which to conclude that UVa's gamma knife service is inefficiently employed.

The existing diagnostic and neuroscience services at CJW are fragmented physically; coalescing these services into the proposed center will increase efficiency of these existing services. The existing parking lots at CJW have insufficient capacity, and CJW has documented the probability of increased parking demand. The proposed parking deck should serve the interest of convenience and increase the efficiency with which existing parking facilities are employed.

20. The need and the availability in the health service area for osteopathic and allopathic services and facilities and the impact on existing and proposed institutional training programs for doctors of osteopathy and medicine at the student, internship, and residency training levels.

Not applicable.

C. RECOMMENDATION

I have reviewed the application and subsequent submissions of CJW Johnston-Willis Medical Center. I have heard from counsel to the applicant in support of its application, and from the staff of the Division of Certificate of Public Need who evaluated the proposal. I have considered the recommendation issued by the board of directors of the .

Based on my assessment, I have concluded that the application submitted by CJW to (i) introduce a gamma knife service; (ii) construct a neuroscience and outpatient diagnostic center – to include the gamma knife service, among others; and (iii) construct a three-story, 700-space parking deck in Chesterfield County merits approval and should receive a certificate of public need (COPN), subject to the following two conditions, as authorized by Virginia Code Section 32.1-102.2 C, viz.:

- 1. That CJW provide neuroscience and outpatient diagnostic services to all patients without regard to ability to pay, to be evinced by –**
 - (a) The provision of general neuroscience and outpatient diagnostic services as charity care equating to a level of at least 0.8 percent of gross patient revenue,**
 - (b) The provision of gamma knife surgery, specifically, as charity care equating to a level of at least 1.5 percent of gross patient revenue; and**
 - (c) The submission annually to DCOPN and CVHPA of an audited or otherwise certified financial statement documenting compliance with the preceding charity care provisions for the first three years following operation of the neuroscience and diagnostic center; and**

2. That each neurosurgeon using the gamma knife at CJW should be properly credentialed for gamma knife procedures, and this credentialing information should be contained in each neurosurgeon's medical staff file.

The specific reasons for my recommendation include:

- (i) The proposed overall project is substantially compliant with applicable standards and provisions of the State Medical Facilities Plan (SMFP);
- (ii) When considered together, the review of and actions taken by the Central Virginia Health Planning Agency (CVHPA) in relation to this application, essentially constitute a recommendation of approval of the proposed project, provided issuance of the attendant COPN is conditioned on the provision of an enhanced level of charity care;
- (iii) The International Radiosurgery Support Association (IRSA) has observed that gamma knife treatment has become the standard of care throughout the world as an alternative to open skull craniotomy, and has stated that CJW would be an "excellent geographic location" for the establishment of a gamma knife facility to serve local trigeminal neuralgia patients and the many Virginia residents diagnosed with various neurological conditions, over 230 of whom annually leave the state for gamma knife treatment;
- (iv) CJW has an open medical staff, which would allow any qualified neurosurgeon trained in gamma knife surgery to provide such treatment to his or her patients at CJW, and CJW has expressed willingness to train neurosurgical residents on the gamma knife unit;
- (v) Construction of the proposed neuroscience and outpatient diagnostic center offers many benefits relating to efficiency and patient and physician convenience that consolidating the various services involved would entail;
- (vi) Parking facilities at CJW are limited and documentation shows a clear and current need for additional parking space, such as the proposed 700-space parking deck would provide; and
- (vii) Projected costs and charges for the gamma knife service, and projected costs relating to construction of the neuroscience and diagnostic center and the parking deck are generally reasonable.

Respectfully submitted,

Douglas R. Harris, J.D.
Adjudication Officer